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| APPLICATION NO.                 | FILING DATE    | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO |
|---------------------------------|----------------|----------------------|-------------------------|-----------------|
| 09/771,277                      | 01/26/2001     | Jose A. Olivares     | 4250.2.6                | 7977            |
| 21552 7                         | 590 04/15/2004 |                      | EXAMINER                |                 |
| MADSON & METCALF                |                |                      | STARSIAK, JOHN S        |                 |
| GATEWAY TOWER WEST<br>SUITE 900 |                |                      | ART UNIT                | PAPER NUMBER    |
| 15 WEST SOUTH TEMPLE            |                |                      | 1753                    |                 |
| SALT LAKE CITY, UT 84101        |                |                      | DATE MAILED: 04/15/2004 |                 |

Please find below and/or attached an Office communication concerning this application or proceeding.

|  | Application No.   | Applicant(s)   |  |  |  |
|--|---|--|--|--|--|
| . i  | 09/771,277  | OLIVARES ET AL.  |  |  |  |
| Office Action Summary  |   | Art Unit   |  |  |  |
| omec Action cummary  | Examiner  | 1753   |  |  |  |
| The MAILING DATE of this communication ap  | John S. Starsiak Jr.  | l  |  |  |  |
| Period for Reply   | pears on the cover shoot with the o   | on coponacinos analeses  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPL THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1. after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a rep - If NO period for reply is specified above, the maximum statutory period - Failure to reply within the set or extended period for reply will, by statut Any reply received by the Office later than three months after the mailine earned patent term adjustment. See 37 CFR 1.704(b). | 136(a). In no event, however, may a reply be tim<br>oly within the statutory minimum of thirty (30) days<br>will apply and will expire SIX (6) MONTHS from<br>e. cause the application to become ABANDONE   | nely filed s will be considered timely. the mailing date of this communication. D (35 U.S.C. § 133). |  |  |  |
| Status   |   |  |  |  |  |
| 1) Responsive to communication(s) filed on 12 J  | lanuarv 2004.   |  |  |  |  |
|  | This action is <b>FINAL</b> . 2b)⊠ This action is non-final.  |  |  |  |  |
| 3) Since this application is in condition for allowa   | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.   |  |  |  |  |
| Disposition of Claims  |   |  |  |  |  |
| 4) Claim(s) 1,2,5-22,24-27 and 29-50 is/are pend 4a) Of the above claim(s) is/are withdra 5) □ Claim(s) is/are allowed. 6) □ Claim(s) 1, 2, 5-22, 24-26, and 29-50 is/are refered to. 8) □ Claim(s) 27 is/are objected to. 8) □ Claim(s) are subject to restriction and/or Application Papers  9) □ The specification is objected to by the Examin 10) □ The drawing(s) filed on is/are: a) □ accompany and applicant may not request that any objection to the Replacement drawing sheet(s) including the correct 11) □ The oath or declaration is objected to by the Examin 2.                 | ejected.  or election requirement.  er.  cepted or b) objected to by the leading of the drawing | e 37 CFR 1.85(a).<br>jected to. See 37 CFR 1.121(d).   |  |  |  |
| Priority under 35 U.S.C. § 119   |   |  |  |  |  |
| 12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of:  1. Certified copies of the priority document 2. Certified copies of the priority document 3. Copies of the certified copies of the priority application from the International Bureat* See the attached detailed Office action for a list  | nts have been received.<br>Its have been received in Applicationity documents have been received in PCT Rule 17.2(a)).  | on No ed in this National Stage  |  |  |  |
| Attachment(s)  |   |  |  |  |  |
| 1) Notice of References Cited (PTO-892)  | 4) Interview Summary  |  |  |  |  |
| Notice of Draftsperson's Patent Drawing Review (PTO-948)     Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08 Paper No(s)/Mail Date  | Paper No(s)/Mail Da<br>5) Notice of Informal P<br>6) Other:   | ate<br>Patent Application (PTO-152)  |  |  |  |

Art Unit: 1753

#### **DETAILED ACTION**

## Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, 5-18, and 40-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hanning et al in view of Beal & Sudmeier.

Hanning et al. teaches [ABSTRACT]: "... a new laser-fluorescence detector for capillary electrophoresis (CE) is described. The detector is based on transverse illumination and collection of the emitted fluorescent light via total internal reflection along the separation capillary. The capillary is coated with a low refractive index fluoropolymer and serves as a liquid core waveguide (LCW). The emitted light is detected end-on with a CCD camera at the capillary exit... Full four-color DNA sequencing is also demonstrated... The concept should be highly suitable for capillary array detection." Hanning et al. teaches [page 3424, left-hand column]: "The separation capillary is externally coated with a polymer (Teflon AF, DuPont, Wilmington, DE) with a lower refractive index (RI) than the separation medium." Hanning et al. teaches [page 3425, left hand column]: "The laser was operated at 30 mW." Hanning et al. teaches [page 3425, left hand column]: "In this way, the 10-90% intensity width of the laser beam in the axial direction at the capillary was estimated to be 25 μm.".

Art Unit: 1753

experiments the capillary was filled with a viscous 7.0% (w/v) solution of linear poly(dimethylacrylamide) in a 1 x TBE(0.1 M tris, 0.1M borate, 2 mM EDTA0, 7M urea buffer.". Hanning et al. teaches [page 3424, right hand column and page 3425, left hand column]: "The emitted fluorescent light was guided ~ 50 mm to the end of the capillary. The end of the capillary was placed in a liquid-filled chamber. The opposite wall of which was made of a planar glass plate, at the focal point of a 27-mm-focal width f/0.9 aspheric condenser lens...The primary light was absorbed by one or more glass filters... Finally, the capillary end was imaged by a 50-mm camera objective... onto a thermoelectrically cooled CCD camera...The collected images were stored and evaluated by means of WinView software...on an IBM-compatible PC. Hanning et al. teaches [page 3425, left hand column]: "The length of gel-filled capillary from the injection end to the illumination zone was ~300 mm.". Hanning et al. teaches [page 3425, left hand column]: "The sample was injected at 4kV for 20s and electrophoresed at 5kV.". The only difference between the claims and Hanning et al. is that the light source of Hanning et al. is stationary with respect to the capillary and the claims recite that the light source "scans" the capillary along the longitudinal axis of the capillary. Beale & Sudmeier teaches that "scanning" the detection system along the longitudinal axis of the capillary has advantages over a stationary detection system. Specifically Beale & Sudmeier teaches [page 3367, left hand column]: "The capability to monitor the progress of the separation process or to dynamically alter the length of the separation bed by scanning the entire capillary offers several advantages over conventional instrumentation. Separation time can be optimized since the duration of the run need

Art Unit: 1753

only be long enough to resolve the components of interest. Thus, sample throughout will be increased as the solutes do not need to migrate through the entire length of the separation bed.". It would have been obvious to one of ordinary skill in the art at the time of the invention to add means for "scanning" the laser to the device of Hanning et al. in order to gain the advantages taught by Beale & Sudmeier.

Claims 19-22, 24-26,30-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hanning et al. in view of Beale & Sudmeier and Li et al.

For the modification of Hanning et al in view of Beale & Sudmeier see the rejection above. The device of Hanning et al. is illustrated only schematically. Li et al. Discloses a liquid core waveguide detector in detail. In Li et al. (see Fig. 1) the emitted light passes from the end of the capillary through a fiber optic to the photodiode. The fiber optic allows emitted light to pass out of the cell while forming part of the cell wall (no liquid can flow out of the end of the cell). Also, the use of a fiber optic allows flexibility of the location of the photodetecting element(s) of a liquid core wavelength detector, i.e., the photodetecting element(s) do not need to be aligned on the longitudinal axis of the capillary and more of the light exiting the end of the capillary would reach the CCD camera. It would have been obvious to one of ordinary skill in the art in the time of the invention to provide the device of Hanning et al. with a fiber optic because of the advantages recited above.

Art Unit: 1753

Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hanning et al. in view of Beale & Sudmeier and Li et al. as applied to claim 19 above, and further in view of Kim et al.

In Hanning et al. the fluorescent light is filtered by a filter characterized in the following way: "The primary light was absorbed by one or two glass filters (OG530, Schottz Glaswerke, Mainz, Germany). Claim 28 recites filtering the fluorescent light with a "narrow bandpass filter". The use of "narrow bandpass filters" in notoriously well-known in the laser-induced fluorescence detection art. For example, Li et al. teaches [page 938, left hand column]: "Band-pass filters 10 nm in width, centered at 540, 560, 580, and 610 nm... selectively transmit the fluorescence generated from C, A, G and T fragments to the photomultiplier tube (PMT) detector, respectively". Either the filter(s) of Hanning et al. can be characterized as "narrow bandpass filters" or it would have been obvious to one of ordinary skill in the art at the time of the invention to substitute a "narrow bandpass filter" for the filter(s) of Hanning et al. since they provide the same function.

### Allowable Subject Matter

Claim 27 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

An appropriate search of the prior art failed to reveal any reference(s) which explicitly teaches or fairly suggest a device for separating and detecting particles

Art Unit: 1753

comprising: a capillary having a first end and a second end the capillary filled with a buffer solution, the capillary having a coating that transforms the capillary into a light wave guide; a first reservoir in fluid communication with the first end of the capillary, the first reservoir configured to contain buffer solution; a second reservoir in fluid communication with the second end of the capillary, the second reservoir configured to contain buffer solution; an electrical source for applying a voltage across the capillary, the voltage causing a fluorescently labeled particle positioned within the capillary, the fluorescently labeled particle emits light after excitation beam, the excitation source being capable of exciting fluorescently labeled particles at more than one position along the capillary wherein the excitation beam is rastered along part or all of the length of the capillary; a light detector positioned to collect fluorescent light emitted from excited fluorescently labeled particle located within the capillary, wherein the light detector comprises: a filter optic coupled end-on to the capillary; low-level optics selected from a group consisting of: photomultipliers, photodiodes, and CCD cameras; a high band pass filter with a wavelength greater than about 500 nm; and a notch filter.

Applicant's arguments filed January 12, 2004 have been fully considered but they are not persuasive.

The applicant fails to address the critical issue, i.e. what does the Beale & Sudmeier teach and/or suggest. Beale & Sudmeier et al. explicitly discloses using a modified "Mathies" type detection system (which previously was used to "scan" an array of capillaries) to "scan" the length of a single capillary. However, Beale & Sudmeier

Art Unit: 1753

does not explicitly disclose that only a "Mathies" type detection system can be used to "scan" a single capillary. Moreover, in the first paragraph of Beale & Sudmeier in which they recite the advantages of "scanning" the entire capillary during an electrophoretic separation, there is no recitation of any of the particulars of a "Mathies" type detection system. Hence, it is the examiner's position is that Beale & Sudmeier teaches/suggests modifying any stationary detection system so that it would be a scanning detector system. None of the applicant's arguments directly address the examiner's position. Most of the applicant's arguments are based on an incorrect interpretation of the examiner's rejection, i.e., nowhere in the rejection does the examiner state that it would be obvious to substitute a "Mathies" type detection system for the detection system disclosed in Hanning et al. Applicant's final argument that since Beale & Sudmeier "appeared in the literature one year prior to Hanning et al." Hanning et al. should have been "motivated to use a scanning light source" is not well-taken for the following reasons. One, if applicant's argument is correct the only rejections based upon prior art would be those based on anticipation (102 rejections). Two, the paper of Hanning et al. was received by Analytical Chemistry, approximately six months before the publication of Beale & Sudmeier. Hence without positive evidence, it is just as likely that the reason Hanning et al. did not use a "scanning" detector is that the experiments described in Hanning et al. were performed before the publication of Beale & Sudmeier.

Art Unit: 1753

#### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John S. Starsiak Jr. whose telephone number is (571) 272-1346. The examiner can normally be reached on Monday to Friday from 7:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen, can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

John S. Starsiak Jr.

02 April 2004

NAM NGUTEN
SUPERVISORY PATENT EXAMINER